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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/310,740 05/13/99 BROWN

S 37-49

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HM22/0619

EXAMINER

WILLIAMS, P

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

06/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/310,740	BROWN ET AL.	
	Examiner	Art Unit	
	Pernell V. Williams	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 20-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 28-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1,6</u> . | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of **1-19 and 28-36** in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 20-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

An action on the merits of claims 1-19 and 28-36 is contained herein.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 5, 14, 18, 19, 28-33, and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,925,670 (Schmidt).

The instant claims 1, 5, 14, 18 and 19 set forth methods of coating a substrate by applying biologically active material, optionally with one or more excipients, and a cover coating, to a substrate which is then split into individual dosage units and removed from said active material. Claims 28-33 and 35-36 set forth the compositions made by the methods above.

Schmidt teaches methods of making a solid dosage form consisting the steps of coating an active agent onto a removable substrate (column 2 lines 20-30), optionally

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including excipients (column 3 lines 33-44), and a cover coating (column 4 lines 25-28), and dividing the combination into individual dosage units (column 2 lines 50-55), and removing the substrate prior to administration (column 5 lines 20-27). Schmidt teaches the steps of maintaining an active agent particle size of 1-20 microns (column 3 lines 60-65), adding layers of multiple active agents (column 4 lines 18-25). Schmidt also teaches the compositions created by the methods cited *supra* (claims 1-3). For these reasons, Schmidt is seen to teach all the elements contained within the instant claims, and therefore anticipates the instantly claimed inventions.

2. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by WIPO Application 91/16041 (Tovey).

The instant claim sets forth a wafer for pharmaceutical administration, comprising a biologically active agent and possessing a thickness of less than 2 mm.

Tovey teaches a pharmaceutical wafer with a thickness of 0.3 to 1.0 mm (page 2 lines 22-34). For this reason, Tovey is seen to teach all the elements contained within the instant claim, and therefore anticipates the instantly claimed invention.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102((e), f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 2-4, 6-13, and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt as applied to claims 1, 5, and 14 above, and further in view of Tovey and U.S. Patent 3,764,538 (Shelffo).

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Determining the scope and contents of the prior art

Schmidt discloses as essential steps for creating a solid dosage pharmaceutical wafer all of the following:

- Coating an active agent onto a removable substrate (column 2 lines 20-30);
- Dividing the combination into individual dosage units (column 2 lines 50-55);
- Optionally including excipients (column 3 lines 33-44);
- Optionally maintaining an active agent particle size of 1-20 microns (column 3 lines 60-65);
- Optionally adding layers of multiple active agents (column 4 lines 18-25); and,
- Optionally adding one or more intermediate and protective coating layers which are impermeable to air and moisture, and may be opaque (column 4 lines 25-30).

Tovey discloses as essential steps for creating a solid dosage pharmaceutical wafer all of the following:

- Coating an active agent onto a substrate using various printer-type arrangements (page 6 lines 23-27); and,
- Maintaining a wafer thickness of 0.3-1.0 mm (page 2 lines 31-34).

Shelffo discloses electrostatic methods which bring a charged-sensing powder into contact with a charged substrate as means for printing dry electroscopic powders onto a substrate, with particle sizes ranging from 1-75 microns (column 1 lines 50-51; column 7 lines 5-43).

Ascertaining the differences between the prior art and the claims at issue

The instant application claims as essential steps for creating a solid dosage pharmaceutical wafer all of the following:

- Coating an active agent onto a removable substrate;
- Dividing the combination into individual dosage units;
- Optionally including excipients;
- Optionally maintaining an active agent particle size of 1-200 microns;
- Optionally adding layers of multiple active agents;
- Optionally wherein said active agent is a dry powder upon application; and,
- Optionally using an electrostatic printing means, in various orientations, for coating active agent onto a substrate.

Schmidt and the instant application differ in that Schmidt does not set forth using electrostatic means to apply the active agent to the substrate. The instant application, Schmidt, and Tovey are all seen to be in the same field of endeavor which is the art of pharmaceutical wafer formulation.

Resolving the level of ordinary skill in the pertinent art

In light of Tovey and Shelffo, it would have been obvious to the practitioner of ordinary skill in this art at the time the invention was made to add the steps including using electrostatic means to apply an active agent to the substrate, because Tovey teaches that any printer-type arrangement may be used to apply an active ingredient to a

substrate. A practitioner of ordinary skill in the art would be motivated to use electrostatic means to apply said active agent, motivated by the disclosure in Shelffo that electrostatic printing is a well-known means of applying a solid powder to a substrate. The methods as disclosed by Shelffo are also seen to render obvious the instant claims 7-10, which set forth the orientation of the substrate relative to the electroscopic powder, because although not specifically stating the orientation, the disclosure of Shelffo is seen to read upon all orientations as set forth, as long as the charge sensing powder is brought into contact with the electrostatically charged substrate.

Considering objective evidence present in the application indicating obviousness or nonobviousness

It is noted that there has not been presented any evidence of record to obviate the rejection cited *supra*. The disclosures of the methods as set forth in the prior art patents are seen to render the instantly claimed methods *prima facie* obvious. Hence, there is no evidence in the present application to support nonobviousness.


Claims 1-19 and 28-36 are not allowed at this time.

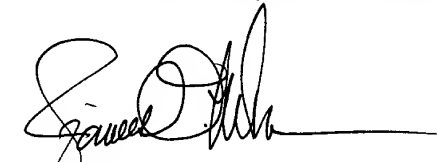
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pernell V. Williams, whose telephone number is

(703) 308-4645. The examiner can normally be reached from 8AM to 4:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, Examiner James O. Wilson may be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


pw
June 14, 2000


James O. Wilson
Primary Examiner
Art Unit 1623